

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2012 has been entered.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-14, 38-43, 46-48, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al (6,602,241) in view of Jay et al (6,494,862). Makower et al disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site using a phased array transducer. The imaging is used to guide the positioning and rotational orientation of

the catheter within the vasculature to ensure proper placement of the penetrator to the target site. Makower discloses that the desired treatment site can include a periadventitial area outside but close to the vessel wall (col 3, lines 1-9). Imaging 360 degrees about the vessel wall using a phased array positioned at the catheter tip will inherently include imaging a thickness of at least a portion of the vessel wall as evidenced by Jenkins (5,109,859), see figures 1A,B. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The treatment agent can include a sustained release composition in a carrier (col 16, lines 50-67, col 17, lines 1-5). The treatment agent can include an inflammation-inducing agent directed to a specific binding site to stimulate angiogenesis (col 1-2). The device is advanced through the vessel wall to an extravascular treatment site and therefore would provide the treatment site as set forth in claims 5,6. Makower et al fails to disclose the delivery device comprises a balloon and a delivery lumen coupled to the exterior surface of the balloon where the balloon is used to urge the delivery lumen in a direction of the wall of the blood vessel. Ray et al disclose the use of a delivery lumen coupled to the exterior surface of a balloon where inflation of the balloon causes the delivery lumen to pivot in the direction of a vessel in the body in order to improve its positioning at a desired location. It would have been obvious to one skilled in the art to have modified Makower et al such that it includes a balloon which is inflated to cause the delivery lumen to move in a direction of the wall of the vessel. The advantage of such is to improve the chances of properly positioning the needle in its desired location. The use of Makower et al would appear to include treatment sites as set forth in claims 7,8 however, the use of the device for any known treatment site in the body would have been obvious to one skilled in the art given the disclosed agents provided by Makower et al. With respect to claim 10, in the absence of any showing of criticality, the specific size of the carrier used would have been an obvious design choice of known equivalents in the art. With respect to claims 11-13, 41-43,46,

47,51,52, in the absence of any showing of criticality, the specific type of drug delivered would have been an obvious selection of known drugs and their uses based upon the desired patient treatment. The catheter includes a flexible needle device for both penetrating the vessel wall and for delivering treatment material. The device is considered be a "ribbon member deflector" which deflects the tip of the needle.

Claims 4,32,54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Ray et al as applied to claims 1,38 above, and further in view of Selmon et al (6,514,217). Makower et al as modified by Ray et al disclose the invention as discussed above but fail to disclose the use of optical imaging such as OCT. Makower et al disclose that other types of imaging devices can be used instead of ultrasound. The use of both ultrasound and OCT are well known in the art for imaging blood vessels as seen for example in Selmon et al. It would have been obvious to one skilled in the art to have further modified Makower et al such that the imaging modality used is OCT. Such a modification merely involves the substitution of one known type of imaging modality for another.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Ray et al as applied to claim 9 above, and further in view of Segal (2002/0131974). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the use of an opsonin-inhibitor. As disclosed in Segal the use of an opsonin-inhibitor is known in order to modulate the response to carriers put into a subject for treatment purposes. It would have been obvious to one skilled in the art to have further modified Makower et al such that the carrier includes an opsonin-inhibitor as is a well known expedient in the art of drug delivery.

Claims 12, 13,41-43,47,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Ray et al as applied to claims 1,38 above,

and further in view of Slepian et al (5,749,915). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the agents set forth. The use of materials such as polycaprolactone and polyurethane for treatments involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles. The materials can be inflammation inducing and are heated when introduced into the body. It would have been obvious to one skilled in the art to have modified Makower et al such that materials, such as polycaprolactone and polyurethane in carriers such as metallic particles are used to further treat the vessels as is a well known expedient in the art.

Claims 44-45,49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Ray et al as applied to claims 1,38 above, and further in view of Yock (5,676,151) or Ouchi (6,338,717). Makower et al as modified disclose the invention as discussed above but fails to specifically disclose the use of a balloon through which the imaging occurs. It is a well known expedient in the art to provide a balloon at the end of a device paced in the body in order to the device to be fixed at a desired location. Examples of medical devices which include a balloon at the tip of the device and an imaging means which images through a transparent material of the balloon is shown in Yock and Ouchi. It would have been obvious to one skilled in the art to have further modified Makower et al such that the catheter includes a balloon through which the imaging occurs as such is a well known expedient for positioning a catheter in the body for diagnosis or treatment.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Ray et al as applied to claim 1 above, and further in view of Myers et al (5,725,551). Makower et al as modified disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment

site. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The imaging transducer is located in a lumen of the catheter and can include an ultrasound imaging device. Makower et al fail to disclose measuring the thickness of the vessel wall imaged. It is well known in the art that ultrasound can be used to determine vessel wall thickness. An example of such is seen in Myers et al. It would have been obvious to one skilled in the art to have used the ultrasound imaging device of Makower et al to further measure the thickness of the vessel wall and use the thickness measurement in addition to the images to further ascertain the path to the treatment site.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1,3-14,32,38-55 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is (571)272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737

RSS